1635

Attorney Docket No. 23878.0005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#5 / K.T. 7/29

ELECTION

In re patent application of:

Paula SUNDSTROM

Serial No. 09/725,010 Group Art Unit: 1635

Filed: 29 November 2000 Examiner: J. Zara

For: METHODS FOR ALTERING THE EXPRESSION OF HYPHAL-SPECIFIC GENES

REPLY TO RESTRICTION REQUIREMENT

Commissioner for Patents
Washington, D.C. 20231

Sir:

In reply to the Office Action dated 25 June 2002, Paper No. 4, in which restriction was required, Applicant hereby elects, with traverse, Group III (claims 1-7, 11, 18-21, 27-32) drawn to methods of interfering with expression of hyphal-specific genes in a fungus comprising manipulating the binding of DNA BP to *cis* regulatory elements, for prosecution in the subject application. Further, Applicant hereby elects, with traverse, the following species for prosecution in the subject application:

Election 1: Hyphal-specific gene (*HWP*1)
Election 2: *Cis*-regulatory element (NIT2 binding site)
Election 3: DNA binding protein (GAT99)

Examiner's requirement for restriction is not proper because the Examiner has failed to establish a *prima facie* instance of serious burden and has failed to establish that the alleged inventions are distinct from each other. Moreover, the Examiner has improperly read limitations into generic claim 1 based upon its dependent claims.

I. No serious burden on Examiner exists to examine members of Markush group together

The Examiner has asserted that the Applicant must indicate which hyphal-specific gene (listed in claims 18-19) and cis regulatory element, DNA BP, or binding domain (listed in claims 28-32) are to be included in the elected Group. Applicant respectfully submits that an election of species is not proper because the members of the Markush groups are relatively small in number.

Applicant asserts that it is only proper to require restriction when there would be a serious burden upon the Examiner. According to MPEP § 803.02, if the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the Examiner must examine all the members of the Markush group in the claim on the merits. For instance, the Markush group in claim 18 contains only five members that are related to hyphal-specific genes (HYR1, ECE1, ALS3, CHS2, and SAP6). Moreover, the Markush group in claim 30 contains only three members that are related to GATA-factor binding proteins containing a NIT2 binding domain (GAT99, GAT-1, or GATA-like binding proteins).

Since the Markush groups contain a small number of members, examining the members of the Markush groups together will pose no additional burden on the Examiner. Accordingly, Applicant respectfully submits that it is not proper to restrict the application in this manner.

II. No serious burden on Examiner exists to examine Groups I-X together

Examiner requirement for restriction is not proper. It is only proper to require restriction if there would be a serious burden on the Examiner if restriction is not required. A *prima facie* instance of serious burden only exists when the Examiner shows separate classification, separate status in the art, or a different field of search among the claimed inventions. *See* MPEP § 803(A) and (B). Applicant respectfully submits that the Examiner has failed to establish a *prima facie* instance of serious burden.

No serious burden would be placed on the Examiner to examine claims 1-6, 9, 15-21, 27-32 of proposed Group I, claims 1-6, 10, 18-21, 27-33 of proposed Group II, claims 1-7, 11, 18-21, 27-32 of proposed Group III, claims 1-8, 13, 18-21, 27-32 of proposed Group V, and claims 35-41 of proposed Group IX together because the Examiner has failed to show

separate classification. Indeed, these Groups of claims all belong to the same class and subclass, i.e., class 453, subclass 6. Hence, examining these five groups of claims together will pose no additional burden on the Examiner. Accordingly, it is not proper to restrict the application in the manner and, thus, the Examiner must examine the claims of Group I, Group II, Group III, Group V, and Group IX together on the merits. *See* MPEP § 803(A) and (B).

Additionally, no serious burden would be placed on the Examiner to examine claims 1-7, 12, 18-21, 27-32 of proposed group IV, and claims 1-8, 14, 18-21, 27-32 of proposed Group VI together because the Examiner has failed to show separated classification. Indeed, these Groups of claims all belong to the same class and subclass, i.e., class 536, subclass 24.5. Hence, examining these two groups of claims together will pose no additional burden on the Examiner. Accordingly, it is not proper to restrict the application in the manner and, thus, the Examiner must examine the claims of Group IV and Group VI together on the merits. *Supra.*

Finally, no serious burden would be placed on the Examiner to examine claims 1, 18-27 of proposed Group VII, and claims 1 and 34 of proposed Group VIII together because the Examiner has failed to establish separate classification. Indeed, these Groups of claims all belong to the same class and subclass, i.e., class 514, subclass 44. Hence, examining these two groups of claims together will pose no additional burden on the Examiner. Accordingly, it is not proper to restrict the application in the manner and, thus, the Examiner must examine the claims of Group VII and Group VIII together on the merits. *Supra.*

III. Restriction of Groups I-IX is improper because inventions are related

The Examiner's requirement for restriction of Groups I-IX is improper because the Examiner has failed to establish that the alleged inventions are distinct from each other. The Examiner alleges that Groups I-IX are unrelated, stating that the "inventions are unrelated if it can be shown that they [inventions] are not disclosed together as capable of use together and they have different modes of operation." Paper No. 4 at page 4. Applicant asserts that Groups I-IX are related and has sufficiently disclosed that the Groups are capable of use together.

The claims are directed to a methodology for inhibiting cell growth of a fungus by interfering with the transcription of hyphal specific genes. Claim 1 is generic and claims 2-34

follow thereon. Applicant's specification discloses that control of transcription of hyphal-specific genes is mediated by *cis*-acting sequences that interact with DNA binding proteins to repress or activate transcription in response to environmental signals. *See, e.g.*, Specification at page 22, lines 18-24. Indeed, the inventions of alleged Groups I-IX are related because it is the presence of common *cis*-acting elements in different genes that indicates a mechanism for coordinate regulation of a set of genes for a given set of environmental conditions. *See, e.g.*, Specification at page 22, lines 30-32.

Moreover, the Examiner has further asserted that Groups I-IX "comprise different and distinct methods," concluding that "the end result of each Group's methods are different." Paper No. 4 at page 4. The Examiner has asserted that the end result of each alleged Groups' method comprises, for example, the "manipulation of environmental factors," the "manipulation of signal transduction pathways," and the "manipulation of DNA BP binding to cis regulatory elements." The Examiner has not listed the end result, but rather, limitations of the dependent claims for the interfering step flowing from independent claim 1.

Applicant submits that the end results of each of the alleged "distinct methods" are not different. Indeed, the end result of each alleged method is the same, which is the inhibition of cell growth of a fungus. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the present restriction requirement, based upon improper restriction of Groups I-IX.

IV. Restriction of Groups I-X is improper because inventions are related

Finally, the Examiner has alleged that Groups I-X are "unrelated," concluding that "the nucleic acids of Group X are not used in the methods of Groups I-IX." Paper No. 4 at pages 4-5. Applicant respectfully directs the Examiner's attention to claim 21, where the nucleic acid sequence of claim 42 has been used in the method of alleged Groups I-VII. Additionally, the nucleic acid sequence of claim 43 comprises the 3' flanking region of the hyphal-specific gene, *HWP*1. *See* Specification at page 6, lines 30-33. This nucleic acid sequence is related to the methods of alleged Groups I-VII, as the 3' flanking region may contain *cis* acting sequences that may control transcription of the hyphal-specific gene. Therefore, the Examiner's requirement for restriction is not proper because the Examiner has failed to establish that the alleged inventions are distinct from each other. Accordingly, Applicant respectfully requests

reconsideration and withdrawal of the present restriction requirement, based upon improper restriction of Groups I-X.

V. Conclusion

In light of the foregoing arguments, the Examiner's requirement for restriction is not proper because the Examiner has failed to establish a *prima facie* instance of serious burden and has failed to establish that the alleged inventions are distinct from each other. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the present restriction requirement, based upon improper restriction of Groups I-X, as well as improper restriction to a specific hyphal-specific gene, *cis* regulatory element, DNA BP, or DNA BP domain. 37 C.F.R. § 1.475 and § 1.143.

Applicant, of course, reserves the right to file divisional applications covering the subject matter of the non-elected claims.

If there are any fees due in connection with the filing of this reply, please charge the fees to undersigned's Deposit Account No. 50-1067. If any extension of time is not accounted for, such extension is requested and the associated fee should be charged to said deposit account.

Receipt of the initial Office Action on the merits is awaited.

Respectfully submitted,

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